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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/604,943      | 08/28/2003  | Itzhak Bentwich      | 050992.0300.CPUS07  | 1942             |

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| EXAMINER |
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SHIN, DANA H

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| ART UNIT | PAPER NUMBER |
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1635

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05/30/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/604,943 | <b>Applicant(s)</b><br>BENTWICH, ITZHAK |  |
|                              | <b>Examiner</b><br>Dana Shin         | <b>Art Unit</b><br>1635                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21,23-25,27,28,35 and 36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21,23-25,27,28,35 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5-9-07</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

This Office action is in response to the communications filed on May 9, 2007.

Currently, claims 21, 23-25, 27-28, and 35-36 are pending. Applicant has cancelled claims 22, 26, 29-34, and 37-40.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Arguments and Amendments***

#### **Withdrawn Rejections**

Any rejections not repeated in this Office action are hereby withdrawn.

#### **New Rejections Necessitated by Amendments**

##### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21 and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Cowsert et al. (US 6,107,091).

The claims are drawn to an isolated nucleic acid consisting of at least 18 nucleotides of SEQ ID NO:480, wherein the sequence of the nucleic acid comprises the complement of a sequence at least 67.7% identical to SEQ ID NO:131.

Cowsert et al. teach an isolated nucleic acid consisting of 18 nucleotides that is identified as SEQ ID NO:69, wherein the complementary nucleic acids of SEQ ID NO:69 are at least 67.7% identical to instantly claimed SEQ ID NOs:480 and 131.

Claims 21, 23-24, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Robbins et al. (WO 2001/30362 A2).

The claims are drawn to an isolated nucleic acid consisting of at least 18 nucleotides of SEQ ID NO:477, wherein the sequence of the nucleic acid comprises the complement of a sequence at least 67.7% identical to SEQ ID NO:128.

Robbins et al. teach isolated nucleic acids consisting of 19 nucleotides that are identified as SEQ ID NOs:2873, 2874, and 2875, wherein the nucleic acids of SEQ ID NOs:2873-2875 are at least 67.7% identical to instantly claimed SEQ ID NOs:477 and 128. They also teach vectors comprising the isolated nucleic acids of SEQ ID NOs:2873-2875.

Claims 21 and 23-24 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Bennett et al. (WO 2002/88162 A1).

The claims are drawn to an isolated nucleic acid consisting of at least 18 nucleotides of SEQ ID NO:482, wherein the sequence of the nucleic acid comprises at least 67.7% identity to SEQ ID NO:133, and an isolated nucleic acid comprising at least 67.7% identical to SEQ ID NO:128.

Bennett et al. teach an isolated nucleic acid consisting of 20 nucleotides that is identified as SEQ ID NO:69, wherein the SEQ ID NO:69 has at least 67.7% identity to both SEQ ID NOs:482 and 133. They also teach an isolated nucleic acid consisting of 20 nucleotides that is identified as SEQ ID NO:61, wherein the nucleotides of SEQ ID NO:61 are at least 67.7% identity to SEQ ID NO:128.

Claims 21 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Aldwinckle et al. (US 6,903,247 B2).

The claims are drawn to an isolated nucleic acid consisting of 18-120 nucleotides wherein the sequence of the nucleic acid comprises the complement of a sequence at least 67.7% identical to at least 18 nucleotides of SEQ ID NO:131.

Aldwinckle et al. teach an isolated nucleic acid consisting of 20 nucleotides that is identified as SEQ ID NO:18, wherein the sequence of SEQ ID NO:18 comprises a complementary sequence to instantly claimed SEQ ID NO:131, wherein the complementary sequence of SEQ ID NO:18 is at least 67.7% identical to SEQ ID NO:131.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 23-25, 27-28, and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robbins et al. (WO 2001/30362 A2) as applied to claims 21, 23-24, and 35 above, and further in view of Fire et al. (US 6,506,559 B1).

The claims are drawn to an isolated nucleic acid and a vector comprising the nucleic acid, wherein the nucleic acid comprises at least 18 consecutive nucleotides of SEQ ID NO:477.

Robbins et al. teach isolated nucleic acids consisting of 19 nucleotides that are identified as SEQ ID NOs:2873, 2874, and 2875, wherein the nucleic acids of SEQ ID NOs:2873-2875 are at least 67.7% identical to instantly claimed SEQ ID NOs:477. For example, see sequence alignment between instantly claimed SEQ ID NO:477 (Qy) and SEQ ID NO:2873 (Db) shown below. They teach that SEQ ID NOs:2873-2875 are cyclin H ribozyme binding site sequences. They also teach vectors comprising the isolated nucleic acids of SEQ ID NOs:2873-2875. Robbins et al. do not teach nucleic acids comprising at least 18 consecutive nucleotides of SEQ ID NO:477.

|    |   |                  |    |
|----|---|------------------|----|
| Qy | 4 | CTTTATTTCCACATTA | 19 |
|    |   |                  |    |
| Db | 4 | CTTAATTTCCACCTTA | 19 |

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Fire et al. teach that sequence identity of nucleic acids may be optimized by alignment algorithms known in the art, and therefore, the nucleotide sequence of an isolated nucleic acid can comprise insertions, deletions, and single point mutations or it can comprise 100% sequence identity to the target sequence (columns 4 and 7-8).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the sequence identity of SEQ ID NO:2873 of Robinson et al. by using alignment algorithms known in the art as taught by Fire et al.

One of ordinary skill in the art would have been motivated to modify or optimize the ribozyme binding site sequences of Robinson et al. (SEQ ID NOs:2873-2875) in order to increase the efficacy or degree of target gene inhibition, with a reasonable expectation of success, by utilizing alignment algorithms and calculations available in the art as taught by Fire et al. The skilled artisan would have been further motivated to do so because Fire et al. expressly teach that inhibitory nucleic acid molecules can comprise insertions, mutations, deletions without affecting the target-binding ability of the molecules, and therefore, the skilled artisan would have had a reasonable expectation of arriving at the instantly claimed nucleic acid through routine optimization experimentation. Accordingly, the instantly claimed invention taken as a whole would have been *prima facie* obvious at the time of filing.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin  
Examiner  
Art Unit 1635

  
J. DOUGLAS SCHULTZ, PH.D.  
SUPERVISORY PATENT EXAMINER